



Billing Code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Tuesday, October 20th, 2020, from 11:00 a.m. until 4:30 p.m., and Wednesday, October 21, 2020, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at on the SACHRP web site when this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Tuesday, October 20, 2020, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. The meeting will begin with presentation of

recommendations on the interpretation of the public health surveillance exclusion, 45 CFR 46.102(l)(2) and 46.102(k). This will be followed by a panel review of ethical considerations regarding “justice” within 45 CFR 46, and how this concept may affect the actions of IRBs. The following day continues with a discussion of recommendations on risks to bystanders posed by the research setting. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

The public will have an opportunity to comment to the SACHRP during the meeting’s public comment session or by submitting written public comment. Persons who wish to provide public comment should review instructions at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html> and respond by midnight Wednesday, October 14, 2020, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at SACHRP@hhs.gov. Verbal comments will be limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Dated: September 18, 2020.

Julia G. Gorey,

Executive Director, SACHRP,

Office for Human Research Protections.

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